



AnaptysBio Announces Fourth Quarter and Full Year 2019 Financial Results and Provides Pipeline Updates

March 2, 2020

- Interim Top-Line Data From Etokimab ECLIPSE Phase 2 Trial in Chronic Rhinosinusitis with Nasal Polyps Anticipated in First Half of 2020
- Reported Positive Topline Data from Interim Analysis of GALLOP Phase 2 Clinical Trial of ANB019 Monotherapy in Moderate-to-Severe Generalized Pustular Psoriasis and Anticipate Additional Clinical Data and Regulatory Update During 2020
- Phase 1 Trial of Company's Third Wholly-Owned Program, ANB030, an anti-PD-1 Agonist Antibody, Anticipated in First Half of 2020 Following IND Submission in Q4 2019
- GlaxoSmithKline (GSK) Announced BLA Submission of Dostarlimab, a PD-1 Antagonist Antibody Partnered With AnaptysBio, in Endometrial Cancer

SAN DIEGO, March 02, 2020 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on emerging immune control mechanisms applicable to inflammation and immuno-oncology indications, today reported operating results for the fourth quarter and year ended December 31, 2019 and provided pipeline updates.

"We look forward to three Phase 2 clinical trial readouts from our wholly-owned etokimab and ANB019 programs and the expansion of our pipeline with ANB030 and ANB032 during 2020," said Hamza Suria, president and chief executive officer of AnaptysBio. "AnaptysBio is a capital-efficient antibody discovery and development engine that has been validated by the advancement of 7 internally-generated therapeutics to the clinic over the last 4 years, and we look forward to anticipated FDA approval of dostarlimab under our GSK partnership."

Etokimab (ANB020 Anti-IL-33) Program

- AnaptysBio is conducting a randomized, placebo-controlled Phase 2 trial in approximately 100 adult patients with chronic rhinosinusitis with nasal polyps, also referred to as the ECLIPSE trial. Patients are being treated with two multi-dosing frequencies of subcutaneously-administered etokimab or placebo, each in combination with mometasone furoate nasal spray as background therapy. The Company anticipates topline data from an interim analysis of the ECLIPSE trial in the first half of 2020.
- The Company previously announced data from its ATLAS trial, a Phase 2b randomized, double-blinded, placebo-controlled, multi-dose study in approximately 300 adult patients treated with etokimab in moderate-to-severe atopic dermatitis. Each of the etokimab dosing arms failed to meet the primary endpoint of the trial, which was demonstration of statistically greater improvement in the Eczema Area and Severity Index (EASI) relative placebo at week 16. AnaptysBio has discontinued development of etokimab in moderate-to-severe atopic dermatitis.
- The Company has decided to postpone the initiation of its planned Phase 2b etokimab clinical trial in eosinophilic asthma, a multi-dose, randomized, double-blinded, placebo-controlled trial in 300-400 patients, until results are available from the ECLIPSE trial.

ANB019 (Anti-IL-36 Receptor) Program

- In September, AnaptysBio announced positive topline data from an interim analysis of its Phase 2 clinical trial of ANB019 monotherapy in moderate-to-severe generalized pustular psoriasis, or GPP, also known as the GALLOP trial. In this interim analysis, both patients achieved the primary endpoint of disease score improvement at Day 29 and Day 113 without requiring rescue therapy, demonstrated rapid and sustained mJDA score improvement, with reduction of 58% at Day 8 and 63% at Day 113, and showed complete clearance of skin pustules by Day 8 and through Day 113, with CRP levels decreasing to nearly normal. Enrollment is ongoing in the GALLOP study, and the Company anticipates additional clinical data and a regulatory strategy update for the development of ANB019 in GPP during 2020.
- The Company is also conducting a randomized, placebo-controlled, multi-dose Phase 2 trial in 50 patients with palmoplantar pustulosis, or PPP, also known as the POPLAR trial, with topline data anticipated in the second half of 2020.
- AnaptysBio has taken steps to enhance enrollment in the GALLOP and POPLAR trials, including expansion of clinical trial sites and countries.

ANB030 (Anti-PD-1 Agonist) Program

- ANB030 is a wholly-owned antibody that binds PD-1 in an agonistic manner, leading to reduced T cell activity and anti-inflammatory effects *in vivo*. Genetic mutations in the PD-1 pathway are associated with increased susceptibility to various inflammatory conditions and we believe ANB030 has the potential to suppress inflammatory diseases by restoring insufficient PD-1-mediated negative signaling on activated T cells. The Company plans to focus future clinical development of ANB030 on certain autoimmune diseases where PD-1 checkpoint receptor function may be under-represented, submitted an Investigational New Drug Application (IND) in the fourth quarter of 2019 and plans to initiate a Phase 1 clinical trial in the first half of 2020. Preclinical data from the ANB030 was presented in June at the 2019 FOCIS Annual Meeting.

ANB032 (Anti-BTLA Modulator) Program

- Our fourth wholly-owned program is an anti-BTLA modulator antibody, known as ANB032, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. Mutations in the BTLA signaling pathway are associated with human inflammatory disease and we believe ANB032 silences pro-inflammatory signaling by modulating BTLA binding to HVEM. We anticipate filing an IND for ANB032 in the second half of 2020.

Dostarlimab (Anti-PD-1 Antagonist) Program Partnered with GSK

- GSK has recently announced that a first BLA filing for dostarlimab, an AnaptysBio-generated PD-1 antagonist antibody under partnership with TESARO, a GSK company, occurred in the fourth quarter of 2019 for the treatment of endometrial cancer. AnaptysBio anticipates receiving a \$10.0 million cash milestone payment upon acceptance of this BLA filing and a \$20.0 million cash milestone upon first FDA approval of dostarlimab. Including additional cash milestones due upon future development and commercialization of dostarlimab, TSR-022, an AnaptysBio-generated TIM-3 antibody, and TSR-033, an AnaptysBio-generated LAG-3 antibody, AnaptysBio can potentially receive a total of \$1.1 billion in aggregate milestone payments under this GSK partnership. In addition, AnaptysBio is due a 4% to 8% royalty from GSK, tiered upon global sales, for each of the aforementioned programs.

Board of Directors

- In September, the Company appointed Laura J. Hamill to its board of directors. Most recently, Ms. Hamill served as Executive Vice President, Worldwide Commercial Operations, for Gilead Sciences, where she was involved in the strategic direction and long-term planning of the organization. Previously, Ms. Hamill held a number of US and international executive roles at Amgen, culminating with Senior Vice President and General Manager where she led ~\$20B in U.S. commercial operations.

Fourth Quarter and Full Year Financial Results

- Cash, cash equivalents and investments totaled \$428.5 million as of December 31, 2019 compared to \$500.2 million as of December 31, 2018, for a decrease of \$71.7 million. The decrease relates primarily to cash used for operating activities.
- Collaboration revenue was \$3.0 million and \$8.0 million for the three months and year ended December 31, 2019, which related to a milestone for initiation of a Phase 2 trial for TSR-033, the anti-LAG-3 antibody partnered with TESARO, a GlaxoSmithKline (GSK) company, compared to zero and \$5.0 million for the three and year ended December 31, 2018.
- Research and development expenses were \$21.4 million and \$99.3 million for the three months and year ended December 31, 2019, compared to \$15.9 million and \$56.2 million for the three months and year ended December 31, 2018. The increase was due primarily to continued advancement of the Company's etokimab and ANB019 clinical programs and additional personnel-related expenses, including share-based compensation.
- General and administrative expenses were \$3.8 million and \$16.1 million for the three months and year ended December 31, 2019, compared to \$3.7 million and \$15.5 million for the three months and year ended December 31, 2018. The increase was due primarily to personnel-related expenses, including share-based compensation.
- Net loss was \$20.3 million and \$97.3 million for the three months and year ended December 31, 2019, or a net loss per share of \$0.75 and \$3.60, compared to a net loss of \$17.0 million and \$61.7 million for the three months and year ended December 31, 2018, or a net loss per share of \$0.64 and \$2.50.

Financial Guidance

AnaptysBio expects its net cash burn in 2020 will be approximately \$60.0 million, and that its cash, cash equivalents and investments will fund its current operating plan at least into 2023.

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation. The Company's proprietary anti-inflammatory pipeline includes its anti-IL-33 antibody etokimab,

previously referred to as ANB020, for the treatment of chronic rhinosinusitis with nasal polyps, or CRSwNP, and eosinophilic asthma; its anti-IL-36R antibody ANB019 for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP; its anti-PD-1 agonist program, ANB030, for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated, and its BTLA modulator program, ANB032, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. AnaptysBio's antibody pipeline has been developed using its proprietary somatic hypermutation, or SHM platform, which uses in vitro SHM for antibody discovery and is designed to replicate key features of the human immune system to overcome the limitations of competing antibody discovery technologies. AnaptysBio has also developed multiple therapeutic antibodies in an immuno-oncology partnership with TESARO, a GSK company, including an anti-PD-1 antagonist antibody (dostarlimab (TSR-042)), an anti-TIM-3 antagonist antibody (TSR-022) and an anti-LAG-3 antagonist antibody (TSR-033), and an inflammation partnership with Celgene, including an anti-PD-1 checkpoint agonist antibody (CC-90006) currently in clinical development.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the timing of the release of data from our clinical trials, including etokimab's Phase 2 clinical trial in adult patients with CRSwNP and ANB019's Phase 2 clinical trials in GPP and PPP, the timing of and our ability to launch a Phase 2b clinical trial of etokimab in eosinophilic asthma patients, the timing of a regulatory strategy update for GPP, the timing of initiation of a Phase 1 clinical trial for ANB030, the timing of an IND filing for ANB032, the milestones and royalty payments to be received under the GSK partnership, and our projected 2020 cash burn and cash runway. Statements including words such as "plan," "continue," "expect," or "ongoing" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company's ability to advance its product candidates, obtain regulatory approval of and ultimately commercialize its product candidates, the timing and results of preclinical and clinical trials, the company's ability to fund development activities and achieve development goals, the company's ability to protect intellectual property and other risks and uncertainties described under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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ANAPTYSBIO, INC. CONSOLIDATED BALANCE SHEETS (in thousands, except par value)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 171,017	\$ 113,596
Australian tax incentive receivable	—	174
Short-term investments	203,210	313,486
Prepaid expenses and other current assets	3,506	6,960
Total current assets	377,733	434,216
Property and equipment, net	1,618	1,445
Long-term investments	54,305	73,128
Other long-term assets	1,481	148
Restricted cash	60	60
Total assets	<u>\$ 435,197</u>	<u>\$ 508,997</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 16,237	\$ 5,443

Accrued expenses	11,052	8,761
Notes payable, current portion	1,375	7,574
Other current liabilities	871	58
Total current liabilities	29,535	21,836
Other long-term liabilities	654	796
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.001 par value, 500,000 shares authorized, 27,255 shares and 26,922 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	27	27
Additional paid in capital	648,669	633,251
Accumulated other comprehensive income (loss)	338	(223)
Accumulated deficit	(244,026)	(146,690)
Total stockholders' equity	405,008	486,365
Total liabilities, preferred stock and stockholders' equity	\$ 435,197	\$ 508,997

ANAPTYSBIO, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Collaboration revenue	\$ 3,000	\$ —	\$ 8,000	\$ 5,000
Operating expenses:				
Research and development	21,426	15,920	99,338	56,196
General and administrative	3,832	3,743	16,094	15,526
Total operating expenses	25,258	19,663	115,432	71,722
Loss from operations	(22,258)	(19,663)	(107,432)	(66,722)
Other income (expense), net:				
Interest expense	(200)	(365)	(1,041)	(1,652)
Interest income	2,282	2,834	10,984	6,685
Other (expense) income, net	(109)	8	1	(159)
Total other income (expense), net	1,973	2,477	9,944	4,874
Loss before income taxes	(20,285)	(17,186)	(97,488)	(61,848)
Provision for income taxes	22	192	152	192
Net loss	(20,263)	(16,994)	(97,336)	(61,656)
Other comprehensive income (loss):				
Unrealized income (loss) on available for sale securities, net of tax of (\$36), \$55, \$153, and \$55, respectively	(142)	318	561	203
Comprehensive loss	\$ (20,405)	\$ (16,676)	\$ (96,775)	\$ (61,453)
Net loss per common share:				
Basic and diluted	\$ (0.75)	\$ (0.64)	\$ (3.60)	\$ (2.50)
Weighted-average number of shares outstanding:				
Basic and diluted	27,154	26,788	27,059	24,673



Source: AnaptysBio, Inc.